it works. He asked how important is the euphoric effect; and went on to say that a certain number are depressed and therefore an anti-depressant drug would be better.

Dr. Hollingsworth seconded Dr. Reidenberg's comment and said that it is vital we know more about CNS effects, nor-epinephrine, growth hormone, insulin . . . we ought to start with animal models. She then said that a large group of obese are never hungry—how then can you evaluate an anorxigenic in these patients? . . . polydipsia is very common on the other hand . . . I have not been able to rationalize placing fat children on drugs.

Dr. Prout then stated that we accept the potential value of these drugs. He next said that it is very important to avoid bias on the part of the person who analyzes the data (this remark seemed to be directed at the statistics). The panel agreed that patients should be at least 20 percent over the Metropolitan ideal weights to be included in a study.

Dr. Goldberg said that we must exclude hypertensives if Phase 1 data suggest that the drug be contraindicated.

Dr. Brey voiced the opinion that of course there are standard reference drugs which are effective. Dr. Reidenberg replied that Dr. Henry Simmons had just indicated that efficacy had not been conclusively demonstrated for any of these drugs.

Dr. Christakis made a plea for caution and responsibility on the part of the profession—the burden is on industry—in view of the great potential for harm from these drugs.

Dr. Prout felt that 12 weeks was the minimum duration of therapy with these drugs that would provide meaningful data. Dr. Bray felt that 6–8 weeks was enough. Dr. Hollingsworth pointed out that obesity was a life-long disease. Dr. Goldberg said that the number of weeks should be put in the package insert.

Dr. Knox then asked Dr. Prout how efficacy could be defined. The reply was that the Federal Register contained the statement that these drugs have short-term efficacy and therefore the Panel could not consider the question as to whether there was a medical significance involved, in other words we must accept any statistically significant difference as acceptable evidence of efficacy. (Dr. Prout followed up by saying that in his opinion none of these drugs were of any value and that he would not use them).

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MEMORANDUM

APRIL 12, 1971.

To: Henry E. Simmons, Director, Bureau of Drugs, BD–1.
From: Barrett Scoville, M.D., Deputy Director, DNDP, BD–120.
Subject: Brief abstract of meeting of advisory group on the drug treatment of obesity, April 6, 1971.

A group of consultants with a special interest or experience in the drug treatment of obesity convened on April 6 for a one-day discussion of the questions in the attached agenda.

The conclusions of the group as expressed by the chairman, Dr. Prout appeared to be essentially the following:

1. Anorectic agents are potentially of value.

2. Long-term follow-up in respect to drug efficacy of patients who have lost weight on a regimen involving Anorectic drugs is not the responsibility of drug manufacturing firms. A short term follow-up of a few weeks could reasonably be asked of drug manufactures.

3. Efficacy of anorectic agents should depend on the demonstration of statistical superiority of drug to placebo. The group, through its chairman, explicitly declined to require "biological" superiority, e.g., some minimum loss in terms of percentage of excess weight.

4. A minimum duration for efficacy trials of 12 weeks was proposed. Labeling claims should reflect the duration of trials.

5. A number of changes in details of the PMA version of second-draft guidelines were proposed. The long "philosophical" discussion of various criteria of efficacy on pp. 11–17 was excluded from discussion.

NOTE.—In view of the long-range implications of the group's conclusions for trials of anorectic agents, particularly insofar as they may relax efficacy criteria,